

510(k) Summary

Date Prepared: August 19, 2013
Revised: September 30, 2013

Manufacturer: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Contact: Elizabeth Wheeler
Regulatory Affairs Specialist
904-741-4400 x 9558

Proprietary Name: Biomet Microfixation Facial PreBent Plates with Virtual Surgical Planning

Common or Usual Name: Bone Plate

Device Classification: Class II

Device Product Code: 76 JEY (21 CFR 872.4760)

Secondary Device Product Code(s): 76 DZJ
90 LLZ

Predicate Device: K121589- Biomet Microfixation Facial Plating System
K120956- VSP System (Medical Modeling)

OCT 02 2013

Device Description:

The Biomet Microfixation Facial PreBent Plates with Virtual Surgical Planning is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation for Facial reconstruction procedures. The plates include variations of straight, angle, curved, L-shape, T-shape, double T-shape, Z-shape, X-shape, Y-shape, double Y-shape, H-shape, triangle, square, rectangle, matrix, orbital floor, LeFort, and chin options with various lengths and thickness. Plates are offered flat or pre-bent. Pre-bent plates are contoured by Biomet Microfixation per surgeon specifications or patient specific anatomical model and include patient specific guides and instruments, of the VSP System (K120956, cleared December 12, 2012). The VSP System is used by Medical Modeling to create the guides, instrumentation and a patient specific anatomical model from CT scans provided by a surgeon. Medical Modeling uses the surgeon information to create the anatomical patient specific model. The anatomical patient specific model is then used to aide in proper alignment and bending of the plates previously cleared under K121589 (cleared 9/21/12). This bending process is conducted at Biomet Microfixation based on our process specification and inspection criteria previously cleared with K121589.

Indications for Use:

These devices are implantable bone plates and bone screws for facial procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed

Possible Risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.

Technological Characteristics:

The subject Facial PreBent Plates with Virtual Surgical Planning devices are identical to the predicate devices in terms of indications, use, material, and design. The only difference between the subject device and the predicate device is that the subject device, is not only shaped based on an anatomical specific model, but also the provided patient specific guides and instruments of the VSP System (K120956, cleared December 12, 2012), where the predicate pre-bent plates are shaped based on an anatomical specific model only. Biomet Microfixation has a process specification for bending plates and an inspection criteria to verify the plate matches the anatomical model. Because the plates are verified to a patient specific model they are 100% verified to the Medical Modeling output, anatomical model, for every case. Therefore, no additional testing was conducted on the subject plates.

Sterility Information:

The plates will be marketed as non-sterile, single-use devices.

Clinical Testing:

Clinical testing was not performed to support this submission.

Non-Clinical Testing:

Non-clinical testing was not performed, as the predicate plates have been previously cleared and the subject devices are identical. We have provided the process specification for bending the plates and inspection criteria for inspecting the output to ensure the proper alignment to the anatomical model.

Substantial Equivalence Conclusion:

When compared to the predicate devices, Biomet Microfixation Facial Plating System (K121589, cleared 09/21/12), substantial equivalence is based on the same indications for use and technological characteristics. The subject devices are identical to the predicate devices, but an update to the labeling will be made to give the option of the prebent plates with Medical Modeling VSP System to include patient specific guides, instruments and anatomical model.

Based on the determination that no clinical or non-clinical testing was deemed necessary, it can be concluded that the subject devices, Facial PreBent Plates with Virtual Surgical Planning, do not raise any new issues of safety and effectiveness and perform as well as the predicate devices. Therefore, we conclude that the subject devices are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

October 2, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Biomet Microfixation
Ms. Elizabeth Wheeler
Regulatory Affairs Specialist
1520 Tradeport Drive
JACKSONVILLE FL 32218-2480

Re: K132600

Trade/Device Name: Biomet Microfixation Facial PreBent Plates with Virtual
Surgical Planning
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZJ, LLZ
Dated: August 30, 2013
Received: September 3, 2013

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Biomet Microfixation
Special 510(k) - Facial PreBent Plates with Virtual Surgical Planning**

Indications for Use

510(k) Number (if known): K132600

Device Name: Biomet Microfixation Facial PreBent Plates with Virtual Surgical Planning

Indications For Use:

These devices are implantable bone plates and bone screws for facial procedures including:

- 1. Fractures**
- 2. Osteotomies**
- 3. Reconstructive procedures**
- 4. Revision procedures where other treatments or devices have failed**

Prescription Use xx AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Michael E. Adjodha -S
2013.10.02 13:18:43 -04'00'**

for AIS